



October 29, 2001

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

WARNING LETTER

SJN-02-04

CERTIFIED MAIL

Return Receipt Requested

Mr. Fred Hintz
President
Trans Caribbean Dairy Corporation
D.b.a. St. Thomas Dairies
P.O. Box 304800
St. Thomas, U.S.V.I. 00803

Dear Mr. Hintz:

On August 27 to 29, 2001, The Food & Drug Administration conducted an inspection of your dairy product and juice processing facility located at Magens Bay Road, St. Thomas, U.S.V.I. Evaluation of the findings from this inspection reveal that the Dairy and juice products produced at your plant are adulterated within the meaning of Section 402 (a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) because they were not manufactured in accordance with the requirements of Title 21, Code of Federal Regulations, Part 110 (21 CFR 110), Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. The deviations found during the inspection include the following:

1. Failure to take adequate precautions to assure that finished packaged milk products are not contaminated with microorganisms or chemicals such as antibiotics or to assure that the products contain added nutrients in the amounts declared on the labels as required by 21 CFR 110.80.

No standard plate count or phosphatase tests are performed on finished milk products. No testing has been performed assure that the Vitamins A & D added to 2% reduced fat milk are present in the amounts indicated on the label.
2. Failure to test or otherwise assure that raw materials used in the manufacture of reconstituted milk do not contain objectionable microorganisms as required by 21 CFR 110.80 (a). Although a general certificate stating that skim milk powder and

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sources is suitable for use in the country of origin, the certificates do not list the specific tests, such as phosphatase or antibiotic tests, performed or the results of the tests. No testing is performed on these ingredients by your firm prior to use in manufacturing milk products.

3. Failure to take action to prevent continued distribution of milk products that tested positive for objectionable microorganisms as required by 21 CFR 110.80.

Samples of 1 gallon containers of whole milk tested on 7/2/01 and of ½ pint containers of whole milk tested on 7/3 & 8/3/01 showed results for total coliforms of "Too Numerous to Count" (TNTC). The products were distributed and there is no record of any action taken to identify the source of the contamination or to ensure that adulterated products were sold to consumers.

4. Failure to verify that the pasteurization system for milk and milk products is appropriately designed and maintained to minimize the potential for the growth of microorganisms as required by 21 CFR 110.80 (b)(2).

During the inspection, the following observations were made concerning the pasteurization equipment:

- a) There was no system in place to prevent unauthorized changes to critical control devices such as the homogenizer used as a timing pump, the HTST temperature recorder and the flow diversion control.
 - b) The holding tube was not designed to assure that product in the tube would maintain a constant flow rate to assure adequate pasteurization.
5. Failure to have a vacuum breaker on the water control valves in the milk and juice processing room to prevent backflow or backsiphonage of wastewater or sewage into the water used for processing as required by 21 CFR 110.37 (b)(5).
 6. Failure to have functioning temperature-monitoring devices on the cold storage tanks used to hold pasteurized milk and juice products as required by 21 CFR 110.40 (e).
 7. Failure to have records or other documentation of the periodic calibration of the official thermometer used for the HTST (High Temperature/Short Time) pasteurization equipment as required by 21 CFR 110.40 (f).

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8. Failure to have adequate screening or other protection against pests in the processing area as required by 21 CFR 110.20 (b)(7).

The screen on the window behind the flow diversion device was broken and live flies were observed in the processing area.

9. Both processing and other equipment in the processing area was not maintained in a manner that would prevent contamination of food products as required by 21 CFR 110.40 (a).

The following equipment deficiencies were reported during the inspection:


- a) The ventilation shafts over the bottle filling area had an accumulation of dust and debris.
- b) The overhead shield of the milk filling machine for ½ gallon containers was not installed during filling operations on 8/27 – 28/01.
- c) The rubber gaskets for the agitator shafts on the mixing tanks were not in place, providing a gap between the shaft and the machine that would allow the introduction of contaminants.

You should take prompt action to correct these deviations and prevent their recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Regulatory actions include seizure and/or injunction.

Please notify this office in writing within 15 working days of your receipt of this letter as to the specific actions that you have taken to correct the noted violations. Your response should include an explanation of the steps taken to prevent similar violations in the future. If corrective actions can not be completed within 15 working days, state the reason for the delay and the time within which corrective actions will be completed.

Your reply should be sent to the U.S. Food & Drug Administration to the attention of Mary L. Mason, Compliance Officer, at the address listed on the letterhead.

Sincerely


Mildred R. Barber
District Director